## EXHIBIT 38

## Compliance Training 2017

New England Distribution Center September 7, 2017

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Regional Compliance Manager (Northeast)

#### Dennis Haskins

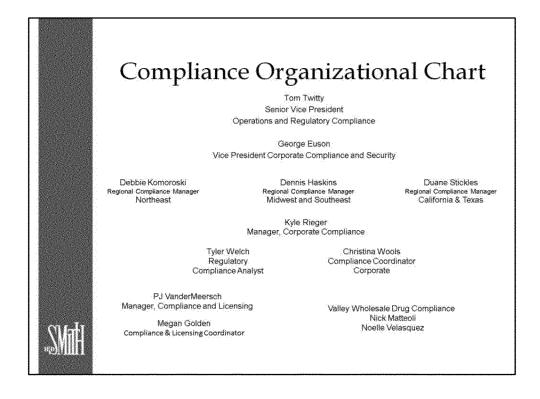
Regional Compliance Manager (Mid-West and SouthEast)



## **Business Ethics....**

"A good company delivers excellent products and services, and a great company does all that and strives to make the world a better place."

- William Ford Jr., Chairman, Ford Motor Co.



## **Understanding Addiction**

- · Affects approximately 15% of population
- · Usually 5% are actively addicted
- Disease knows no socio-economic, age, educational, or professional boundaries
- Every active addict has profound effects on several people, both directly and indirectly
- Tremendous social, financial, and medical impacts
- Death and Injuries
- · Child neglect, abuse, abandonment
- Estimated \$70 billion per year in costs Rx abuse alone

## U. S. Rx Drug Abuse Epidemic

U.S. Center for Disease Control (CDC) has labeled Prescription Drug Abuse a "National Epidemic".

Except for marijuana, the abuse of prescription drugs has surpassed the abuse of illicit drugs, like heroin and cocaine.

CDC 2015 - 52,000 + drug deaths - 142 people die every day from a drug overdose - Death Toll equal to September 11th every 3 weeks.

CDC 2015 – 33,091 Opioid deaths - 91 deaths per day from Opioids including Rx Opioids and heroin (80% of heroin users began with Rx Opioids).

CDC: 2015 – 22,000 people died of Rx Opioid overdoses. Everyday 62 people die as a result of a Rx opioid overdose - approximately one death every 30 minutes.

CDC - Since 1999, the number of Opioid overdoses had quadrupled.

CDC - Since 1999, the number of Rxs for opioids has quadrupled. The amount of Rx opioids sold to pharmacies, hospitals, and doctors' offices has quadrupled, yet there had not been an overall change in the amount of pain that Americans reported.

There are MORE DEATHS from prescription drug overdoses than gun homicides and motor vehicle accidents combined.

These are some of the statistics that demonstrate the scope of the Rx Drug Epidemic.

CDC 2014 - 47,055 people died of drug overdoses (This 3000 - 4000 more than in 2013).

- 61% (28,647) involved Rx Drugs

Majority deaths involved opioids and benzodiazepines. Many OD deaths showed a combination of both.

CDC - 1 in 5 teens report using Rx drugs to get high.

SAMHSA – 2014 report – 4.3 million Americans engaged in the non-medical use of Rx painkillers.

DIRECT CORRELATION BETWEEN THE INCREASE IN PRESCRIBING AND DISPESNING (SALES) and OD DEATHS.

So, what is being done – There must be a multi-faceted approach:

education, addiction counseling, expanded PMP programs, increased enforcement of the drug laws.

# The 5 states with highest death rates (CDC 2015 Statistics)

- 1. West Virginia (41.5 per 100,000)
- 2. New Hampshire (34.3 per 100,000)
- 3. Kentucky (29.9 per 100,000)
- 4. Ohio (29.9 per 100,000)
- 5. Rhode Island (28.2 per 100,000)

#### Estimated World Requirements of Narcotic Drugs 2015 Hydrocodone Top 10 List 10 kilograms 10 Guatemala > 09 Mexico 10 kilograms 20 kilograms > 08 Vietnam > 07 China 20 kilograms > 06 Denmark 25 kilograms > 05 Columbia 50 kilograms > 04 Syrian Republic 50 kilograms > 03 Germany 60 kilograms > 02 Canada 100 kilograms ≥ 01 United States 79,700 kilograms 99.5% U.S. Drug Enforcement Administration Office of Diversion Control

## **RENEWED DOJ FOCUS**

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday August 2, 2017

Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit

AG Jeff Sessions today announced the formation of the Opioid Fraud and Abuse Detection Unit, a new Department of Justice pilot program to utilize data to help combat the devastating opioid crisis that is ravaging families and communities across America. It will focus specifically on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to this prescription opioid epidemic.

Additionally, as part of the program, the Department will fund twelve experienced Assistant United States Attorneys for a three year term to focus solely on investigating and prosecuting health care fraud related to prescription opioids, including pill mill schemes and pharmacies that unlawfully divert or dispense prescription opioids for illegitimate purposes.

### Code of Federal Regulations Title 21 21 CFR 1301.74(b)

Wholesalers and Manufacturers:

The Registrant shall design and operate a system to identify suspicious orders of controlled substances.

The Registrant shall inform the Field Division Office of the D.E.A. in his/her area of suspicious orders when discovered.

Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

<u>21 CFR 1301.36</u>: DEA may suspend or revoke a Wholesaler's registration when it is determined that such registration is inconsistent with the public interest or it is found that there is an imminent danger to the public health or safety.

Let's review some of the Federal Laws that govern our due diligence – legal responsibilities.

The Federal Law for wholesaler and Manufacturers states:

### **DEA** Enforcement

#### Mallinckrodt Pharmaceuticals

July 11, 2017 - \$35 Million Settlement - Failure to Report Suspicious Orders and Recordkeeping Violations

#### **Masters Pharmaceuticals**

 $\label{eq:continuous} \textit{June } 30, 2017-\textit{D.C. Circuit Judge Affirms decision for revocation of Master's DEA Reg.}$ 

September 14, 2015 - DEA Revokes Distributor Registration

#### McKesson

January 17, 2017 - \$150 million civil penalty and DEA Reg. of 4 DCs suspended May 1, 2015 DEA \$150 Million Fine and Registration of 3 DC's Suspended 2012 - DEA \$190 Million Fine 2008 - DEA \$13 Million Settlement

#### **Cardinal Health**

December 23, 2016 - \$44 Million Settlement -Failure to Report Suspicious Orders in New York, Maryland, Florida 2012 - 2 year suspension of DEA reg. at the Lakeland FL facility

#### 2008 - DEA \$34 Million Fine

Rochester Drug Cooperative (RDC)

Value Drug June 25, 2014 - DEA \$4 Million Fine

#### KevSource Medical

2011 - DEA \$320,000.00 Fine 2011 - 1 year suspension of DEA registration.

#### Harvard Drug

2010 - DEA \$8 Million Fine

2010 - 1 year suspension of DEA CII registration.

#### Sunrise Wholesale Inc.

2010 - Surrendered DEAlicense rather than contest the charges.

#### Belico Drug

2007 - \$800,000 Fine and Surrendered DEA Registration for 2 years.



### **DEA** Enforcement

#### Masters Pharmaceutical Distributor DEA Revoked

"A distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate . . . channels."

"Respondent repeatedly failed to contact the pharmacies and obtain an explanation for those orders which were held by the SOMS because they were of unusual size, deviated substantially from a normal pattern, or were of unusual frequency. Accordingly, I find that in numerous instances, the record supports a finding that Respondent failed to contact the pharmacy and obtain an explanation for those orders."

"... a distributor is required to use the most accurate information available to it. I conclude that a distributor must use the [D]URs in evaluating whether a customer's dispensing ratio is suspicious...[respondent's] failure to obtain a new [D]UR rendered its system for detecting suspicious orders ineffective...rendered its suspicious order monitoring system defective."

"ordering the controlled drugs "in quantities disproportionate to the quantity of noncontrolled medications ordered."

"A registrant which "routinely report[s] suspicious orders, yet fill[s] these orders without first determining that [the] order[s] [are] not being diverted . . . may be failing to maintain effective controls against diversion" and engaging in acts which are "inconsistent with the public interest."

What are the reasons their DEA was revoked?

DEA published 308 page decision and order – we can learn from it as it identifies the reasons for the DEA action.

The importance of obtaining dispensing reports is highlighted throughout this document, as well as:

**OSVs** 

Identifying and acting upon suspicious orders.

38 page decision by Circuit Judge affirming DEA revocation – Compliance monitors decisions to learn from them. What is DEA looking for to determine suspicious orders.

#### **Recent Area Actions**

#### Chris Clough PA - New Hampshire

**December 2016** – PA License revoked for over-prescribing opioids **March 2017** –Arrested and charged with receiving kickbacks in exchange for prescribing Subsys.

From August 2013 until October 2014, Clough was paid more than \$41,000 by the drug manufacturer. Clough was charged with one count of conspiracy and seven counts of receipt of kickbacks in relation to a federal health care program. Each charge carries a maximum term of imprisonment of five years and a fine of up to \$250,000.

#### **Identified in New Hampshire Pharmacies**

- Care Pharmacy Rochester (DUR reviewed May 2013).
- Care Pharmacy Dover (DUR reviewed April 2013).

#### Dr. Bharat Patel and Dr. Ramil Mansourov - Urgent Care,

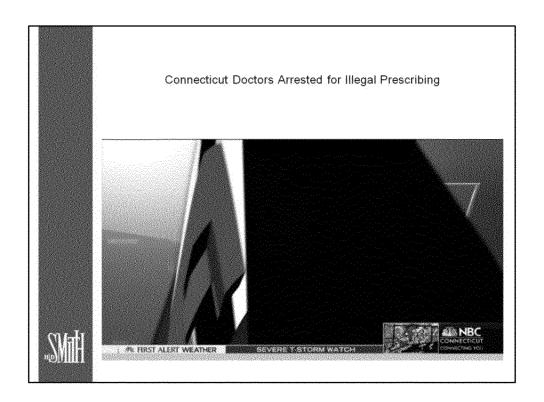
Norwalk, Connecticut

July 2017 - Dr. Patel arrested for writing illegal oxycodone Rxs in exchange for cash.

#### Identified in Connecticut Pharmacy

Vital Care Pharmacy, Norwalk CT (July 2014 DUR reviewed, October 2014 Blocked CS)





### **Hospital Cases - DEA Fines**

(Failed to provide effective controls and procedures to guard against theft and diversion, as required by law.)

#### Abington Memorial Hospital (Pennsylvania)-January 9, 2017 – Hospital fined by DEA \$510,000

Renata Dul RPH - a pharmacist at AMH's inpatient pharmacy stole more than 35,000 pills, including highly addictive painkillers such as oxycodone.

In 2015 Renata Dul was convicted of 25 counts of possession with the intent to distribute oxycodone and was sentenced to six years of imprisonment and three years of supervised release.

#### Massachusetts General Hospital September 28, 2015 - \$2.3 million settlement

MGH, the largest teaching hospital of Harvard Medical School and the largest hospital in MA failed to report to the DEA the theft of more than 15,000 pills – **mostly oxycodone** – stolen from hospital drug-dispensing machines by two nurses.

During the period of 10-4-2011 through 4-1-2015, MGGH failed to report theft of CS.

Most stolen by 2 Nurses - one a pediatric surgery nurse.

## **CSOMP**

CONTROLLED SUBSTANCE ORDER MONITORING PROGRAM

Size - Purchase Limits are set for Families of Drugs - URL  $_{\rm 36}$  different CS Families, each with up to 11 different dosage types.

Standard Plant Levels Individual Levels

Pattern and Frequency

When account alerts on CSOMP - orders are automatically put on hold for review.

DEA Strongly Discourages Wholesalers from identifying the URL to their customers

### **Held Orders**

- Compliance will notify Sales by email of the hold and required information needed.
- Customer Service or Sales Rep should contact the customer as soon as possible.
- Explanation, New or Updated Customer Profile, Dispensing Report, 90-day DUR.
- Family blocked until requested items reviewed.
- Forward Requested Information to Christina Wools, Compliance Coordinator and the Regional Compliance Manager in your area.

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#### Explanation as to why volume has increased

- more nursing homes in area
- new medical practice
- other pharmacy in area out of business

There may be a legitimate reason to adjust their URLs. (price is an unacceptable reason)

## H. D. Smith Due Diligence Program

- Customer Profile
- Purchase History
- Rx History Dispensing Report (PAP must address all concerns brought to the attention of customer 2 weeks)
- On Site Visit
- Compliance Report

Explain length of time it takes to review PAP, including extra time if they request an extension and RCM needs to review the Rx Dispensing Report again to compare it to PAP.

## Important to Remember

Pro-Active steps to avert complications

- Notify Compliance if customer moves from secondary to primary (CSOMP alert).
- Notify Compliance of any actions on customer – DEA, State Actions - Pharmacy Board or Medical Board, Another Supplier's Restrictions.
- Notify Compliance if customer moves its' location.
- Explanation on CSOMP alert must come directly from customer (sales may forward email authored by customer)

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## Customer Reselling H. D. Smith Product To other than end user

· Customer profile prohibits:

I do hereby swear, depose and say that my business does not resell any product purchased from H. D. Smith to any wholesale distributor, re-packager or re-seller entity other than the end user of any kind. In accordance with 28 USC 1746, I declare and affirm, under the penalties for perjury, that the foregoing representations are true and correct.

- · Risk of diversion into gray market
- Could violate H. D. Smith inventory management agreement with manufacturer.

Reminder to customer – this includes non-controls as well as CS.

## Lawful Prescribing and Dispensing

#### Prescriber:

A legal Rx for a controlled substance must be:

- Issued for a legitimate medical purpose
- Issued by a practitioner in the usual course of their professional practice

What are the laws pertaining to legal prescribing and dispensing.

For a CS Rx to be legal:

Most states have laws that mirror the Federal Law.

A Rx for a CS may NOT be issued by a practitioner to treat drug dependence for detox or maintenance, with one exception: BUPRENORPHINE (Suboxone).

The only CS that can be prescribed by a PHYSICIAN to treat narcotic/opioid addicted patients is Buprenorphine.

Specialized training.

Separate DEA number – X.

Limited as to the number of patients they can treat for narcotic addiction.

Follow specific federal guidelines and protocols, regulations and treatment standards. Why? Treating drug dependency is extremely complex.

## CDC Guideline for Prescribing Opioids for Chronic Pain (Published March 2016)

#### Highlights:

- ✓ OPIOIDS ARE NOT FIRST-LINE OR ROUTINE THERAPY FOR CHRONIC PAIN
- ✓ START LOW AND GO SLOW
- ✓ When opioids are needed for acute pain, prescribe no more than needed
- ✓ Discuss benefits and risks and availability of non-opioid therapies with patient.
- ✓ AVOID CONCURRENT BENZODIAZEPINE AND OPIOID PRESCRIBING

The guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

NOTES - The guideline encourages providers to implement best practices for responsible prescribing. These are just some of the guidelines published by CDC.

#### 1. Use non-opioid therapies

Use non-pharmacologic therapies (such as exercise and cognitive behavioral therapy) and non-opioid pharmacologic therapies (such as anti-inflammatories) for chronic pain.

Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

3.Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

## Lawful Prescribing and Dispensing 21 CFR 1306.04

#### **Pharmacist:**

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a <u>Corresponding Responsibility Rests with the Pharmacist</u> who fills the Rx.

An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a legal prescription.

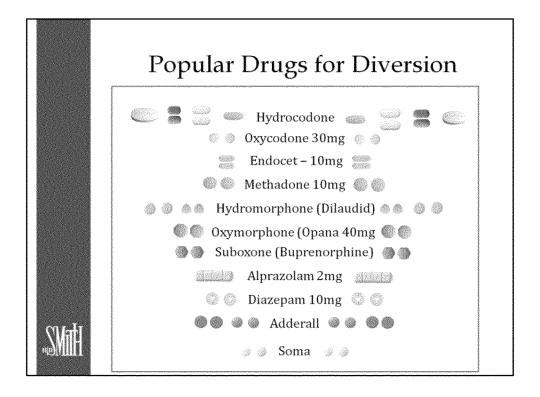
The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Federal Law states:

So, Due Diligence is required of all registrants within this closed system of distribution for CS,

#### Pharmacist's Corresponding Responsibility Source: D.E.A. Pharmacist's Manual 21 CFR 1306.04

A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one's business or professional license (see United States v. Kershman, 555 F.2d 198 [United States Court Of Appeals, Eighth Circuit, 1977]).



Hydocodone – THE most prescribed drug in US. Prescribed more than BP, cholest, heart meds and antibiotics.

Oxycodone 30mg - One of the most popular drugs of abuse in the U.S.

Endocet-10: combination product

Commands a higher street price than other oxycodone/APAP combinations

Why? QA on streets – people buying the drug on the street can identify this drug by the appearance and the markings – 712's. They can sell this drug for more money. - Our case 512s

If customer comes into the pharmacy specifically requesting Endocet-10 – RED FLAG.

Methadone – skip over – later.

Hydromorphone and Oxymorphne very popular drugs of abuse esp CT & NY.

Suboxone: Usually think of this drug to treat opiate addiction.

Popular drug on the street

Opiate naive person will get high.

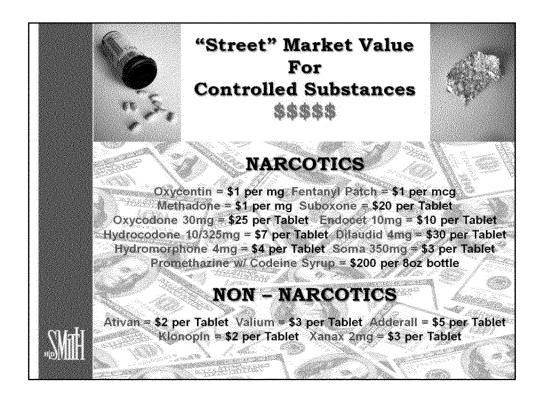
Bought on the street by heroin and RX narcotic abusers to get them through to their next fix if they can't get their hand on their narcotic of choice.

Alprazolam and Diazepam are benzos commonly abused.

Adderal: crushed and snorted like cocaine to get high. High school and colleges.

Abused as academic performance enhancer.

Soma: sch 4 federally in Dec 2011 –popular because potentiates narcotics – 3rd ingredient In commonly abused combination – trinity & holy trinity.



This slide is to give you an idea of the Street Value of these C/S. It helps to explain why these drugs have become such a lucrative business venture.

Prices for these drugs when obtained on prescriptions:

Methadone 10mg #100 tablets = \$25.00 / Street price is \$1.00 per mg or \$10 per tab, 100 tabs = \$1000.00

Dilaudid 4mg #100 tabs = \$100.00 / Street price is \$30.00 per tab, 100 tabs = \$3000.00

Valium/Diazepam 10mg #100 tablets = \$25.00 / Street price is \$3.00 per tab, 100 = \$300.00

# Collateral Damage Consequences of Rx Drug Diversion

**Violence and Crime (Pharmacy Robberies)** 

**Babies Born with Addiction** 

The Number of painkiller-addicted newborns has tripled in the past 10 years



Addiction, Overdose and Death

## Our Responsibility.....

Ensure H. D. Smith is part of the solution rather than adding to the problem of prescription drug abuse in the United States.

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